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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,012	09/14/2001	Colin Gerald Caro	BKY2-0074	7764

7590

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EXAMINER
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PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/10/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/857,012

Applicant(s)

CARO ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3,5,6,12-16 and 24-41 is/are pending in the application.
- 4a) Of the above claim(s) 32-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,5,6,12-16 and 24-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### ***Election/Restrictions***

In the response filed December 1, 2003, Applicant elected Species F (Figures 6A to 6C) for prosecution. The Applicant stated that all the pending claims are readable on the elected invention. However, the Examiner concluded that claims 32-41 should have been indicated as withdrawn because they are clearly drawn to an external stent. The elected species is clearly an internal stent; see page 7, lines 17-19. Therefore, claims 32-41 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No.7 filed December 1, 2003.

### ***Oath/Declaration***

The declaration filed September 14, 2001 is defective because it has no box X'ed under the phrase "the specification of which" so it is unclear where the specification was obtained.

### ***Priority Document***

The copy of the certified priority document is not present in this national stage file so the file is considered incomplete in that regard. Applicant is respectfully requested to provide a photocopy of the official certified copy on file with the International Bureau.

### ***Specification***

The disclosure is objected to because of the following informalities:

There is no brief description of Figures 8 to 12 on page 5 of the specification. A brief description of all the drawings is required; see Rule 74.

Appropriate correction is required.

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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3, 5, 24, and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 6,554,856. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are broader in scope than the patented claims but are read on by the patented claims. Therefore, the Examiner asserts that the present claims are clearly obvious over the patented claims.

### ***Claim Rejections Based Upon Prior Art***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5, 24, and 25 are rejected under 35 U.S.C. 102(b) as anticipated by Caro (WO 95/09585) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Caro (WO 95/09585) alone. Caro anticipates the claim language where the stent with supporting part as claimed is met by the shaped vascular prosthesis that includes "a stent or other structural support of plastic, metal or other material"; see the abstract and page 5, line 28 to page 6, line 10. This shaped tube of Caro especially with a metal stent therein would inherently impose a shape on a vessel it is inserted into because it is designed to be rigid enough to prevent kinking or collapse. The tube of Figure 5 or at least that of Figures 7 and 8 can be inserted into a vein or artery and would presumably not collapse or kink therein because that would make it inoperable; see page 6, lines 24-30.

Alternatively, one reading Caro may come to the conclusion that Caro fails to meet the shape imposition requirement as claimed. However, Fischell teaches that it was known to make stent which support and impose a shape on blood vessels; see column 1, lines 29-57. Therefore, it is the Examiner's position that it would have been obvious to use Fischell as the stent of Caro because Fischell is designed to support and prevent

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the collapse of blood vessels. For this reason, one would be motivated to use it as the means to prevent collapse of kinking of the vascular graft of Caro.

Regarding claim 25 specifically, the tube of Caro is shaped but can be subject to collapse of kinking if not supported. Therefore, it the Examiner's position that flexing to some extent is inherent in Caro because it is made with a material that may kink or collapse without support. Furthermore, virtually all materials have at least some slight elastic deformation properties.

Claims 6 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro (WO 95/09585) in view of Fischell et al (US 5,697,971). Caro meets the claim language as set forth above but fails to disclose the type of stent claimed. However, Fischell teaches that the claimed stent was known to the art; see Figure 2 and Column 2, line 37 to Column 3, line 22. Therefore, it is the Examiner's position that it would have been obvious to use the Fischell stent as the stent of Caro because it would provide a means to prevent collapse and kinking as is the desire of Caro.

Regarding claim 26, the stainless steel of Fischell is an alloy of iron and chromium. It has shape memory in that it retains the shape it is expanded to ;see column 2, lines 36-46.

Regarding claims 28-30, the links as claimed are met by elements (16) of Fischell.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caro and Fischell as applied to claims 6 and 26-30 above, and further in view of Wolff (US 5,104,404). Caro as modified by Fischell has a stent with wave-shaped links but lacks

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the coil structure as claimed. However, Wolff teaches that it was known to make links with coil shapes; see Figure 3. Therefore, it would have been obvious to form the links of Caro as modified by Fischell into a coil form for the same reason as Wolff and since such coils would result in a great deal of flexibility between the "rings."

Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro and Fischell as applied to claims 3, 5, 24, and 25 above, and further in view of Schwartz et al (6,015,387). Caro fails to disclose the monitoring device as claimed. However, Schwartz teaches that such devices were known to the art at the time of the invention; see the abstract and figures. Therefore, it would have been obvious to include a monitoring device in the Caro device for the same reasons that Schwartz uses the same and in order to monitor the blood to see if the swirl flow desired is occurring.

With regard to claims 14 and 15, the Schwartz sensor is electrically connected to the power supply and it electromagnetically transmits a signal to a remote monitor which must have a power supply and recording means to function. This is necessary because the monitor performs a calculation and displays a result; see column 2, lines 25-36. The monitor of Schwartz also uses ultrasound to detect blood flow; see *supra*

### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

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Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic  
Primary Examiner  
Art Unit 3738